



Roundtable: Disclosing Clinical Trial Costs – Why and How Should It Be Done?

17 November 2022

Speakers

Introduction and opening: Dr Natalie Roberts – Executive Director, Médecins Sans Frontières/Doctors Without Borders (MSF) UK

- **Dr Christopher Morten** - Founding Director, Science, Health, and Information Clinic, Columbia Law School, Columbia University; Editor, New York University (NYU) report on Clinical Trial Cost Transparency at the National Institutes of Health: Law and Policy Recommendations
- **Professor Sir Rory Collins** - British Heart Foundation Professor of Medicine & Epidemiology and Head of the Nuffield Department of Population Health, Oxford University; Principal Investigator, UK Biobank
- **Dr Bern-Thomas Nyang'wa** - Medical Director, MSF; Chief investigator, TB-PRACTECAL
- **Dr Duduzile Ndwandwe** - Deputy Director and Vaccinologist, Cochrane South Africa, South African Medical Research Council (SAMRC); Lead, Clinical Trials Registry portfolio (Pan African Clinical Trials Registry and South African National Clinical Trials Registry)
- **Fatima Hassan** - Human rights lawyer, social justice activist, Founder of the Health Justice Initiative (HJI); Recipient of the 2022 Calgary Peace Prize

Moderator: Rachel Cohen - Regional Executive Director, Drugs for Neglected Diseases initiative (DNDi), North America

Background and rationale

This roundtable organised by the MSF Access Campaign was the second in a series of roundtables focused on clinical trial cost transparency. The [first roundtable](#), held in mid-2022, focused on why and how political initiatives and legislation should mandate the disclosure of clinical trials costs. [Participants highlighted](#) how exposing the true costs of clinical trials is an important step towards ensuring accountability, increasing equity in the biomedical research and development (R&D) system, and ultimately to support efforts to increase access to medical products for all who need them.

The second roundtable focused on the disclosure of clinical trial costs: why this should be done and how. In addition to pharmaceutical corporations, there are many other actors that conduct clinical trials, including large-scale phase three clinical trials that are the most expensive to conduct. This includes academic and publicly funded research institutions, as well as non-profits such as DNDi and MSF. At this roundtable, we heard from those directly involved in clinical trials, as well as from academics, legal experts and advocates who are leading efforts to define how clinical trial costs can be disclosed most effectively.

In this report, we aim to capture the key themes that emerged from the second roundtable discussion and consider these to develop recommendations for governments, clinical trial implementers, civil society organisations and other stakeholders to take steps towards the effective disclosure of clinical trial costs.

How can clinical trial costs be disclosed?

The discussion focused primarily on how clinical trial costs can be disclosed, and specifically what data need to be disclosed. This covered clinical trial transparency initiatives in the US and South African contexts, as well as how transferable these approaches may be to other countries. MSF's efforts to improve clinical trial cost transparency were also presented, and the role of other actors, including the World Health Organization (WHO), was discussed.

United States (US)

Dr Christopher Morten presented the [NYU report on clinical trial cost transparency at the US National Institutes of Health \(NIH\)](#), which focuses on the need for clinical trial cost transparency from the NIH and proposes a set of legislative, administrative, and executive-branch measures to achieve this reform. He explained that this research focused on the NIH as it is the “*single largest funder of clinical trials in the world. It invests over \$40 billion in biomedical research every year, and spends over \$15 billion on clinical research, including at least \$6 billion on trials conducted outside the NIH.*” Clinical trial cost transparency from the NIH could “*unlock a meaningful amount of true data on the costs of clinical trial research,*” he added.

The NYU report recommends that the NIH and other holders of clinical trial cost data report a key set of cost items for the overall study, per patient, per year, and (if possible) per site (outlined in more detail in the report). These include:

- Personnel costs (including salary and benefits)
 - Administrative staff
 - Clinical staff
- Materials and supplies
- Clinical procedures
- Site management
 - Site monitoring costs
 - Site retention
 - Other
- Central laboratory
- Equipment
- Other direct costs
 - Publication costs
 - Subawards/consortium/contractual costs
 - Other
- Indirect costs

Morten explained that the disclosure of these data points is recommended specifically because they are useful to those that conduct clinical trials and research, and for advocacy around clinical trials. “*They would facilitate an apples to apples comparison of the costs of various trials in the public and private sector; they are useful to policy makers and legislators as they consider different legal and policy initiatives, help permit more precise measurement of the relative contributions of government and industry to the creation of particular drugs or vaccines or technology; and are useful for identifying waste and inefficiency. We also believe the NIH and partners are already collecting most if not all of this data – which should make it easier for the NIH to collect and share,*” he said.

On the question of how transferable the report's recommendations are to other countries and institutions that fund and conduct clinical trials, Morten explained that while the report examines this issue from a US perspective, and there are practical differences across the world, there are also important commonalities. Morten outlined how the legal analysis for the report engaged with trade secrecy law in the US and other jurisdictions, and their potential impact on disclosure of clinical trial costs. “*The conclusion reached was: no, trade secrecy law and other legal doctrines should not prevent disclosure. This is true in Europe, and under the TRIPS Agreement that's true globally – so I think that's an important transferable lesson,*” he said.

When asked about the response from policy makers to the report's recommendations for reform, Morten explained that while there was "*appreciation for the notion in principle*", there was also "*a hesitance to make this a priority, and some practical concerns*". Morten explained that this spurred transparency advocates to focus on developing legislation that would mandate such data sharing. This approach received "*better traction*", and in April 2022 a group of Senators and Representatives in the US introduced a new piece of legislation called the [Pharmaceutical Research Transparency Act \(PRTA\)](#). He said this legislation would "*mandate disclosure of disaggregated cost data on the costs of clinical trials*" by the NIH, but that "*some of the sponsors of this legislation proposed... mandating disclosure not just by government entities that conduct and fund clinical trials, but also by industry.*"

When asked to comment on the overall importance of pushing for disclosure of clinical trial costs, Morten said he sees it as "*a necessary step towards a more radical reimagining of the way that we create and disseminate drugs.*" "*I think a lot about the public sector taking on a bigger role...not just acting as a piggy bank for industry. Getting to the bottom of how much it costs to run a trial is a part of knowing how much it costs to do all of this work, and with that information we can imagine a more radical transformation,*" he said.

South Africa

Dr Duduzile Ndwandwe explained what information on clinical trial costs is currently captured in South Africa, and some of the challenges around making this information public. Ndwandwe is the leader of Clinical Trial Registry portfolio at Cochrane South Africa, the intramural research unit of the SAMRC, which manages two databases: the Pan African Clinical Trials Registry (PACTR), and the South African National Clinical Trials Registry (SANCTR) funded by the National Department of Health. SANCTR currently collects information regarding the total estimated budget of clinical trials that are conducted in South Africa. This information is not currently collected through PACTR.

Ndwanwe noted that it is mandatory to disclose the total estimated budget of a clinical trial to SANCTR in order for the trial to be registered in South Africa. While the majority of information on the registry is publicly available, the information collected on the budget of the trials is not. She said this is the case because some stakeholders feel that information about clinical trial costs is a "private matter". While there has been some engagement and discussions with stakeholders in South Africa, further discussion is needed about making these clinical trial budgets public, she added.

Ndwanwe said that knowing the costs of clinical trials is important because it can help with challenging "escalated" prices of medical products once on the market. She said, "*For me, it's looking at how much was that particular vaccine in the trial versus what we are costing the government to be able to roll out that vaccine. That's a critical question, because then we are able to challenge and understand that the costing is overpriced and whether the government should be investing in such a drug or looking at generics and other interventions.*"

When asked if the cost of clinical trials in South Africa could be reported similarly to what is recommended in the NYU report presented by Morten, Ndwanwe said it "*should be considered... because when you look at the costs, you can clearly see that the numbers are thumb-sucked, if you like... and you can't argue because at the end of the day we don't have the guidelines or the legislation that mandates that we need to share (that data).*"

Connected to this, Fatima Hassan explained the challenges of trying to access any information about how much clinical trials cost in South Africa currently, since this information is not made *publicly available* by the SANCTR. "*In South Africa, we have a situation where researchers are looking for this data and have been told by different units that this is a function of somebody else – so the Presidency will send you to the Department of Health, the Department of Health will send you to the Department of Science and Technology, who will send you to the Medical Research Council,*" she said.

Hassan stressed that "*the pandemic showed that we are in the middle of a major secrecy crisis*" and that nobody really knows the costs of clinical trials in any country for any medical product. She emphasised that this information should be publicly available. "*Whoever funds the clinical trials often calls the shots, in relation to access, in relation to pricing, in relation to the timing of submission of clinical dossiers to medicine regulators,*

in relation to when generics can enter the market, the transfer of technology and the issuing of voluntary licenses,” she noted. Given the power vested in funders of clinical trials, it is critical to have access to more information about what money is being invested by whom, and particularly the public investment involved so it can be leveraged for access.

Aside from this, Hassan explained that access to information laws is one of the only ways to access information about the costs of clinical trials, but that *“much of this information is subject to non-disclosure agreements and high levels of secrecy.”* As such, Hassan explained that it is critical that *“laws are passed to mandate that this information is made public.”* *“What we have to do in every domestic context, is now start demanding that our lawmakers make this a legal requirement... We can have as many resolutions as we want, as many voluntary asks as we want, but industry will not play ball; it has to be a legal requirement,”* she said.

Ndwandwe explained that the South Africa Good Clinical Practice Guidelines are the guidelines which govern clinical research in South Africa, and that these could be reviewed or amended to include requirements around clinical trial cost transparency as a first step, to ensure that researchers *“conform to that... so that we can hold researchers accountable.”*

MSF

Dr Bern-Thomas Nyang’wa emphasised that MSF recognises the critical need for more publicly available information about clinical trial costs. To this end, MSF published its first [Clinical Trial Transparency Policy \(CTTP\)](#) in October 2022. This policy is a commitment to publishing research protocols, registering clinical trials on appropriate registries, and subsequently publishing clinical trial data in open access formats. These commitments are in line with the [WHO joint statement on public disclosure of results from clinical trials](#), to which MSF is a signatory. Critically, this policy also includes a commitment to publishing a minimum set of cost items for clinical trials carried out by MSF, wherever pragmatic and possible. These cost items draw on the recommendations from the NYU report outlined above.

Highlighting the importance of clinical trial cost transparency, Nyang’wa said, *“We know that clinical trial costs inform policy development and evidence-based decision making. It will promote innovation, particularly from non-traditional actors who are not sure what it would potentially cost; it would help price negotiation, as well as accountability and maximising the impact of public funding and access to medical products.”*

Nyang’wa added that while MSF is only involved in a small number of clinical trials, it is important for the organisation to “walk the talk” while demanding clinical trial cost transparency. *“We are not saying in any way this is easy, but we are saying this is important. Therefore, we need to do it ourselves, and we will continue to demand, to spotlight, to discuss the need for transparency in clinical trial costs,”* he said. As a first step to implementing the CTTP, MSF will aim to publish the costs of the [TB-PRACTECAL](#) clinical trial later this year. TB-PRACTECAL is a phase 2/3 randomised controlled trial (RCT) looking at short, safe and effective regimens for the treatment of DR-TB, led by MSF as lead investigator and sponsor.

Nyang’wa explained that it had been hard to initially budget for TB-PRACTECAL because there is very little information available about how much clinical trials cost. *“In most situations, if any information on clinical trial costs exists, there would just be a gross big number, and you have no idea which component will cost exactly what,”* he shared. He added that while MSF was able to cover the costs of the trial, most institutions will need to know upfront how much their trial may cost.

Role of WHO and the broader international community

The roundtable also discussed the role of WHO and other international actors in supporting the case for clinical trial cost transparency. When discussing the challenges around accessing information about the costs of clinical trials in South Africa and other contexts, Hassan explained that *“this is one of the critical things that the WHO is going to have to engage on...to ensure that there is alignment and accuracy in information that is provided (around clinical trial costs).”*

A number of WHO-level initiatives which could include and recognise the importance of clinical trial costs transparency were mentioned in the discussion. These include the ongoing work related to the World Health Assembly (WHA) 75.8 Clinical Trials Resolution, and critically, the opportunity to legally require disclosure of clinical trial costs as part of the ongoing WHO Pandemic Accord negotiations.

Professor Sir Rory Collins explained the work of [The Good Clinical Trials Collaborative](#), which is funded by the Bill & Melinda Gates Foundation and the Wellcome Trust. This initiative aims to collaboratively develop new international clinical trial guidelines in order to replace the current International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) (ICH-GCP) guidelines.

Collins argued that since the establishment of the ICH in 1990, and their GCP guidelines in 1996, there has been a large increase in the cost and complexity associated with clinical trials. The objective of the ICH-GCP guidelines was to “*provide a unified standard for the European Union (EU), Japan and US to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.*” As such, Collins argued, these guidelines are primarily about “*getting rapid approval*”, and “*are not based... on the scientific underpinnings, the principles, that underlie clinical trials.*” They are also now being applied to RCTs of all medical products.

Collins argued that increased regulation and related bureaucracy on RCTs due to the ICH-GCP guidelines has not only resulted in increased costs for trials, but also in distortion of the research agenda and an increasing dependency on contract research organisations (CROs) for the delivery of clinical trials. Collins said that “*CROs are now a \$70 billion a year industry*”, having not existed before the mid-1990s. He argued that it is in the interest of CROs as well as academic research organisations (AROs) to increase the complexity of undertaking clinical trials, “*because it increases their profits, but this is money being pulled out of the evaluation of treatments.*” Overall, there is an “*undue focus on complying with rules rather than on innovation in the design and conduct of RCTs,*” Collins said.

This issue is addressed in a paper [published by Collins and colleagues](#) just prior to the COVID pandemic, and the [RECOVERY trial](#) later adopted many of the principles outlined in the paper. As part of the work related to the WHA 75.8 Clinical Trial Resolution, the WHO is now in the process of reviewing the Good Clinical Trials Collaborative guidance for RCTs, alongside the current ICH guidelines and others, in order to develop “[new guidance for clinical trials quality and ecosystem strengthening.](#)”

When asked if there is interest in including clinical trial cost transparency in the recommendations of the Good Clinical Trials Collaborative directly, Collins stated it is necessary to engage in the collaboration in order to recommend additional guidelines. However, he agreed it is important to know the cost of clinical trials. “*I think knowing the scale of the costs, knowing what the money is being used for, and then determining if this is a good use of the money, will be very valuable,*” he said.

On the industry response to mandating disclosure of clinical trial costs

During the Q&A discussion, there was a question about whether mandating disclosure of clinical trial costs could “discourage industry from running trials in the jurisdictions that have those mandates”. Morten explained why he believes this would not be the case. “*In large jurisdictions – South Africa, India, US, EU – the number of patients and the existing infrastructure to conduct clinical trials is so important to the global clinical trial enterprise that realistically industry can’t pull out altogether. The same sort of argument could be marshalled against all kinds of regulation of clinical trials – think of results reporting mandates that were very controversial but went into effect in the US 10-20 years ago, or ethical regulations around the treatment of patients or collection of data. Any time industry is regulated, they will respond by threatening to stop doing research, but every time governments take a stand and impose regulations, we find that industry is able to accommodate,*” he said.

Hassan said, *“These are not companies making handbags. These are companies that are researching lifesaving medicines. So this idea that data, costs, protocols can be kept private or kept secret, is something we have to overturn. If they want to move their trials elsewhere then my response is, ‘so be it’. Those are not the companies we want in our countries. We don’t say that we won’t pass laws around protecting workers, or unionisation, or around sexual orientation, or around dignity or around the right to housing just because it might offend some company.”*

In South Africa, where each clinical trial budget is reported but not made publicly available, Ndwandwe noted the concern that recommendations to make this information public through the registry may discourage researchers from registering trials on the registry. However, she explained that this could be tackled by making it a legal requirement by having *“legislation to mandate public disclosure of clinical trial costs.”*

Recommendations

- All governments should take steps to mandate disclosure of clinical trial costs, particularly, but not limited to, when the trials have received public funding. Guidance about the legal, administrative and practical implementation of this can be drawn from the NYU report.
- All actors involved in the delivery of clinical trials should take steps wherever possible to proactively publish the costs of clinical trials, in line with the list of cost items recommended for reporting by the NYU report.
- Stakeholders engaging with the Good Clinical Trial Collaborative guideline development process should advocate for the inclusion of clinical trial cost transparency.
- Governments, civil society organisations and other relevant stakeholders should advocate for the inclusion of clinical trial cost transparency in the ongoing guideline review and development process as part of the WHA 75.8 Clinical Trials Resolution, and for clinical trial cost transparency to be included as a mandatory requirement as part of the WHO Pandemic Accord and other relevant pandemic prevention, preparedness and response processes.